TOPICAL SCAR TREATMENT USING A MIXTURE OF SILICONES

The present invention relates to medical applicator and/or packaging devices, and in particular to such devices for, and methods of, treating bodily surfaces, and a process for their preparation.

Scars resulting from disease (including acne), injury (including burns and scalds) or surgery are undesirable both cosmetically and functionally. Cosmetically, scar tissue is often viewed as unsightly. Functionally, scar tissue often lacks features of undamaged skin such as a normal sense of touch and complete skin integrity.

In the field of wound therapy by for example the application of a wound or burn dressing to or into moist body tissue, it is known that scarring of bodily external surfaces over the healing wound often tends to occur. It is highly desirable to prevent the formation of scar tissue. It is also highly desirable to remove already formed scar tissue from bodily external surfaces without resorting to surgery to do so.

Scar therapy herein thus includes any bodily topical conditions where it is desirable to treat scar-forming tissue prophylactically to prevent scar formation, for example surgical scar or burn scar prevention.

It also includes any bodily topical conditions where it is desirable to treat existing scar tissue to remove it, for example surgical scar or burn scar or birthmark removal.

The term "scar therapeutic agent" when used herein thus refers to and includes any form of matter used in topical application in prophylaxis or treatment of scarring on the body of a patient.

Numerous methods have been developed to treat and/or prevent scars including surgical treatment, pressure treatment, wound collagen implantation and laser ablation, and the topical application of materials such as oils, creams, greases, and aftercare coverings and dressings, such as hydrogel or silicone gel dressings. A major factor in scar treatment or prophylaxis by the topical application of materials such as oils, creams, greases, and aftercare coverings and dressings is to reduce loss

of skin moisture or to actively provide skin hydration. Thus such topically applied materials are often compositions with occlusive or semi-occlusive properties.

Known aftercare coverings and dressings are thus generally, for example occlusive or semi-occlusive layers constructed to be capable of deforming resiliently and to be applied topically.

In one form, these consist of low-scarring cover nets, meshes and webs and other perforate layers, and in another films, membranes or sheets and other imperforate layers.

Often such means include fluid-solid therapeutic agents, such as gels, for example silicone gel sheeting.

Problems associated with such solid gel therapeutic agents include the fact that their inherent tack may not be sufficient to hold them in place on the body.

This is especially the case on certain parts of the body that require a dressing to be highly conformable in order to maintain adhesion, since such gels may lack the necessary conformability. In the extreme case, a fixing bandage may be needed. This can create discomfort on prolonged topical application.

Other problems include the fact that the solid gel film, membrane or sheet may be awkward to separate from itself and, if of lower conformability, may also be cumbersome for patients to apply or to have applied accurately.

Also, if there is any substantial lapse of time with the solid gel in situ on the patient, the solid gel may age deleteriously.

One approach towards solving this problem would be fluid means for treating the bodily external surfaces. However, problems associated with such fluid, for example fluid gel therapeutic agents include the fact that their inherent tack may not be sufficient to hold them in place on the body.

Thus, a fixing bandage may again be needed, which can create discomfort. Known materials with sufficient skin adhesion however will often be inconveniently tacky on the distal face. Known materials often may fail to provide sufficient occlusivity.

Therefore, one of the objects of the present invention is to provide a method of topical scar treatment or prophylaxis using a composition that forms films on the skin that are substantive, semi-occlusive, non-tacky, cosmetically acceptable and easy to apply and remove. Another object of the present invention is to provide a topical applicator for such treatment or prophylaxis.

Accordingly, in one aspect, the present invention provides a medical topical applicator and/or packaging device which comprises a reservoir containing a fluid gel topical scar therapeutic agent, characterised in that the device comprises applicator means for removing the therapeutic agent from the reservoir and applying it topically to a patient.

The term "fluid" is used herein to include a material, containing any fluid gel topical scar therapeutic agent, in any form from a liquid through a paste to a dough, provided that it can be delivered by the present devices.

The medical topical applicator and/or packaging devices of the present invention can be easily manufactured and yet still solve the above problems.

They are particularly advantageous in that they can be used to incorporate a wide variety of scar therapeutic agent materials and include a wide variety of specific embodiments of the present device, so that the device can be tailored for different customer requirements.

The term "medical topical applicator and/or packaging device" is used herein to include means for containing any fluid gel topical scar therapeutic agent that is intended to be applied topically to a patient for treating scar formation or formed scars.

Such medical topical applicator and/or packaging devices are particularly suited to containing and applying a scar therapeutic agent directly and topically to the body.

They may also be used, however, for example to coat a dressing for topical application, which dressing may be separate from or housed in and removed from the medical topical applicator and/or packaging device.

The term "means for removing the therapeutic agent from the reservoir and applying it topically to a patient" when used herein thus also refers to a means for the topical application of a scar therapeutic agent to an appropriate dressing, itself used for topical application.

Thus, where a scar bodily topical condition is treated with a gel topical scar therapeutic agent on a dressing, the latter may comprise cover layers, nets, meshes and webs, backing layers, etc., and optionally an absorbent for the fluid gel.

The means for applying a therapeutic agent topically and directly to a patient on its removal from the medical topical applicator will generally be adapted to providing a therapeutic agent only to the desired area on that patient.

The means for applying a therapeutic agent topically and directly to a patient on its removal from the medical topical applicator are generally but not exclusively means to apply fluid therapeutic agents, such as gels, greases and ointment. It is generally suitable for topical fluid gel topical application, and can provide for the topical application of other therapeutic agents. However, preferred embodiments of the present device include those in which the fluid gel is a polysiloxane fluid gel, in particular those described in detail hereinafter.

In one embodiment of the first aspect of the present invention there is provided an absorbent medical topical applicator and/or packaging device, characterised in that it

a) comprises at least two internal surfaces defining a reservoir containing a fluid gel therapeutic agent, and

b) applicator means for removal of the fluid gel topical scar therapeutic agent from the medical topical applicator and/or packaging device, adapted and in such spatial relationship with the reservoir to coat a patient or a dressing surface with the fluid gel therapeutic agent from the reservoir.

Generally, the reservoir and/or applicator means is provided with apertures, for example holes, openings, perforations or slits. These are adapted such that the fluid gel therapeutic agent may be drawn, spread, diffused, driven, propelled or forced through such apertures into contact with the patient as and when desired.

In some forms of these embodiments it may be desirable that one or more portions of the reservoir and/or topical applicator means are movable relative to the rest of the topical applicator and/or packaging device. Thus, in order to move the fluid gel therapeutic agent into contact with the patient.

The term "movable" includes, for example slidable, slippable, rotatable, revolvable, spinnable, twistable, compressible and squeezable relative to the rest of the topical applicator and/or the rest of the device.

The fluid gel may fill all or only a portion of the reservoir.

In these embodiments of the invention, the reservoir and topical applicator means may not be spatially discrete or separable, or even discrete integers. For example, the applicator means may form part of the reservoir, and, vice versa, the reservoir may be part of the applicator.

In a preferred form of this embodiment of the first aspect of the present invention, a medical topical applicator and/or packaging device is characterised in that the reservoir and topical applicator means together comprise at least two internal surfaces, at least two of which are mutually movable to remove from the reservoir, and apply to a patient, the fluid gel therapeutic agent.

As noted above, the internal surfaces may be

a) deformable or collapsible (for example capable of buckling or resiliently deforming) and/or

b) mutually movable (for example mutually slidable, slippable, rotatable, revolvable, spinnable, twistable, compressible and squeezable relative to the rest of the topical applicator) to apply a therapeutic agent topically and directly to a patient on its removal from the medical topical applicator and/or packaging device.

Examples include all the following:

The device may be in the form of a pen with a roller-ball, -barrel or distributing drum.

Often it is then convenient for the topical applicator means and the reservoir to be in the form of two coaxial hollow cylindrical chambers or other containers of the same diameter but unequal axial length. These may optionally have an intervening wall or barrier, as hereinafter described.

Thus, for example the reservoir containing the fluid gel therapeutic agent may be in the form of a chamber, for example an elongate rigid cylindrical container, one end of which has a large outlet.

This is provided with a second smaller chamber that is coaxial with and of the same diameter as, but of shorter axial length than the larger chamber, and has a larger second outlet through which projects a roller-ball, closely housed by the cylindrical barrel of the second chamber.

The applicator chamber may alternatively be adapted to house a roller-barrel or distributing drum as appropriate next to the reservoir.

A cap that is a push, screw or snap fit on the outside of the second outlet may be used as a means to keep the therapeutic agent in the reservoir until use in this form of this embodiment of the first aspect of the invention.

Here, for example, the applicator means and reservoir have no intervening barrier or connection.

In a similar embodiment of the first aspect of the present invention, the capped outlet may contain a pad, cushion or pillow of foam or an array, matrix, mesh, felt or web of fibres or filaments, to form a foam or fibre pen or brush.

In another form of this embodiment, the applicator means may be provided by a driving means, such as a piston or plunger slidable within the reservoir.

This forms a syringe or pump dispenser, depending on the position of the outlet and/or the stroke of the piston or plunger within the reservoir.

In this form, the piston or plunger slidable within the reservoir may be directly pushed, impelled or driven.

However, depending on the viscosity of the gel inter alia, it may be actuated via a screw thread on the piston or plunger haft, shaft or shank, and a co-operating threaded wheel, disc or annulus rotatably mounted on the reservoir or other part of the device, in the manner of a conventional glue stick.

The applicator means for removal of the fluid gel topical scar therapeutic agent may be at least one wall of the reservoir containing the fluid gel topical scar therapeutic agent that is capable of deforming or collapsing. For example it may buckle or resiliently deform.)

Removal of the topical scar therapeutic agent may then be effected, for example by applying a compressive force to move, drive, propel or force the fluid gel therapeutic agent out of the reservoir into contact with the patient.

A means to keep the therapeutic agent in the reservoir to this point in this form of this embodiment of the first aspect of the present invention

may be a capped and/or stopped outlet, such as a nozzle, pipe, spout or tube from the reservoir.

The cap and/or stopper internal and/or external surfaces may be for example a push, screw or snap fit on and/or in the nozzle or other outlet.

The applicator means for removal of the fluid gel topical scar therapeutic agent may be two opposed walls of the reservoir containing the fluid gel topical scar therapeutic agent that are capable of resiliently or non-resiliently deforming, such as in a conventional deformable ointment tube.

In another form of this embodiment, the topical applicator and reservoir are in the form of essentially one hollow cylindrical chamber or other container.

This has a collapsible end wall and a second, frangible or collapsible end wall, often of foil or foil composite, such as in a conventional suppository packaging.

In this case, the first end wall membrane, film or sheet will usually be integral with the side walls of the patient container.

It additionally will often be of the same material, which will often be transparent or translucent, so that the contents are visible.

Usually, such topical applicator and/or packaging devices are intended and adapted for a plurality of applications to the patient during a scar therapy course.

However such devices intended and adapted for a single application to the patient are not excluded from the scope of the present invention.

In one form of this last embodiment, the medical topical applicator and/or packaging device is in the form of a blister pack.

This has a plurality of blister pack chambers or other containers containing a plurality of doses of fluid gel scar therapeutic agent for topical application.

Usually such embodiments of the topical applicator and/or packaging device of the first aspect of the present invention are adapted for each applying a single application by appropriate means to one patient.

Again, however, such topical applicator and/or packaging devices intended and adapted for a plurality of applications of a scar therapy agent are not excluded from the scope of the present invention.

Individual topical applicator means and reservoir within a plurality of devices are usually interconnected in an array in a blister sheet.

Often these will be mutually delineated by, for example a 'dotted line' of tear, which may fully or only partly breach the blister pack array sheet, or another line or region of brittleness, fragility or weakness.

Such a blister pack array sheet is thus capable of being torn, broken, cracked or snapped along the line or region under appropriate stress to release individual devices.

By varying the material, diameter, length and/or the number of blisters in the blister film, membrane or sheet patient per unit absorbent blister thereof the characteristics of the medical topical applicator and/or packaging device (resilience, compressibility, etc.) can be tailored for different topical applications.

The number of blisters per unit area of the blister sheet is largely determined by the nature of the fluid gel topical scar therapeutic agent in each blister thereof, the space available between blisters for manipulation that is desired, and the material of the blister sheet. It may vary across the sheet, but is generally uniform.

The material of the blister sheet should be sufficiently resilient to maintain all the arrayed blisters in rigid relation to one another. That is, it should be self-supporting.

However, the blister reservoir material should be sufficiently deformable or collapsible to allow the therapeutic agent to be easily expressed.

Apt materials of the blister film, membrane or sheet containing the fluid gel therapeutic agent, and therefore usually the end and side walls of the blister reservoir include those flexible materials recited hereinafter for the same integers generally.

For example flexible polymer materials are apt.

Apt materials of the blister sheet, that the second end wall membrane, film or sheet will usually be or comprise a foil, that is a very thin sheet of metal, such as aluminium.

It may be or comprise a metallised synthetic polymer film, such as a cast membrane or sheet, for example polypropylene backed aluminium or aluminium with a polyester (e.g. PET) lacquer coat.

In another embodiment of the first aspect of the present invention, the spatial relationship between the reservoir and topical applicator means is such that they are discrete and spatially separable integers in use.

In one form of this embodiment, the spatial relationship between the reservoir and topical applicator means is such that the applicator means passes through the fluid gel topical scar therapeutic agent contained in the reservoir on its removal from the rest of the device.

The applicator means is removed from the rest of the applicator, for example the reservoir, and takes with it some of the fluid gel topical scar therapeutic agent contained in the reservoir for topical application to the patient.

Thus, for example the reservoir containing the fluid gel therapeutic agent may be in the form of a chamber, for example an elongate rigid cylindrical container, one end of which has a large outlet.

This is provided with a cap and/or stopper that is a push, screw or snap fit on the outside and/or in the inside of the outlet, which serves as a means to keep the therapeutic agent in the reservoir.

In turn, a haft, shaft or shank is mounted on the cap and/or stopper, usually coaxial with, of shorter axial length than, and projecting into the reservoir. It bears a pad, cushion or pillow of foam or an array, matrix, mesh, felt or web of fibres or filaments, to form a foam or fibre pen or brush.

Again, for example, the applicator means and reservoir have no intervening barrier or connection.

It will be seen that the opposing faces of a film, membrane or sheet, roller ball, piston or plunger, or cap and/or stopper provide surfaces that define the reservoir.

In another embodiment of the first aspect of the present invention, the device is arranged so as to prevent the fluid gel topical scar therapeutic agent contained in the reservoir, from contacting the applicator means at all or until it is desired to remove the agent from the device for topical application.

This may be, for example a deformable, frangible or collapsible film, membrane or sheet between the applicator means and the reservoir, for example an insubstantial film, membrane or sheet.

Alternatively or additionally, it may have at least one line of tear, break, fracture or breach, or other points, or at least one other line or region of brittleness, fragility or weakness.

Such a film, membrane or sheet is thus capable of collapsing and/or tearing, breaking, bursting, cracking or snapping or tearing or breaking down under stress.

Thus, for example a film, membrane or sheet with the properties described above may separate a fluid gel topical scar therapeutic agent contained in one part of a cylindrical syringe barrel that is the reservoir as described hereinbefore, from a piston or plunger slidable within the reservoir.

The piston or plunger slidable within the reservoir may be capable of being directly pushed, impelled or driven, or actuated via a screw thread on the piston or plunger haft, shaft or shank.

This causes the film, membrane or sheet to deform, collapse and/or tear, break, burst, crack or snap, so that the fluid gel topical scar therapeutic agent contained may be removed from the medical topical applicator to be applied to the patient.

Alternatively a reservoir container may be closed for example sealed or shut off, after insertion of the scar therapeutic agent with a deformable membrane, film or sheet as hereinbefore described, at an end remote from a capped outlet for the agent.

The scar therapeutic agent may then be expressed from the device by pressing the deformable membrane, film or sheet.

In all the embodiments of the first aspect of the present invention, the device may be arranged so that the reservoir may decrease in internal diameter towards the end with the outlet for the agent.

For example it may taper down and/or be domed or have at least one step change in internal diameter.

In one form, the outlet for the therapeutic agent from the reservoir may have a collapsible and/or frangible closure membrane, film or sheet, instead of or in addition to any other closure, such as a cap.

The components of the topical applicator and/or packaging device may be formed of the same, similar or different materials. These may include at least one rigid or flexible synthetic polymer (depending self-evidently on the physical properties in any given device), such as a thermoplastic, for example a polyester (e.g. PET) or polyamide (e.g. nylon™), polypropylene or polyethylene, or other polymer materials.

Elastomeric materials may also be used (for example elastomeric polyurethanes) if incorporated together with non-elastomeric materials.

If present, the films, membranes or sheets and the relevant other parts of the reservoir may be held together by heat-sealing, welding (which is particularly apt for thermoplastic materials), adhesive fillets and/or adhesive tape, bands or strips for example.

Suitable materials for any of the foregoing film, membrane or sheets include at least one flexible synthetic polymer, such as a thermoplastic, for example a polyester, for example PET, in particular orientated PET, flexible polypropylene or polyethylene, cellophane™, polyamide (for example nylon™), polyurethane, or other polymer materials.

Elastomeric materials may also be used (for example elastomeric polyurethanes) and may be incorporated together with non-elastomeric material in the film, membrane or sheet.

The other components of the topical applicator and/or container patient may be formed of the same, similar or different materials. These may include at least one rigid synthetic polymer, such as a thermoplastic, for example a polyester (e.g. PET) or polyamide (for example nylon™), polypropylene, polyethylene, or other polymer materials.

Elastomeric materials may also be used (for example elastomeric polyurethanes) if incorporated together with non-elastomeric material in the film, membrane or sheet.

Other materials that may be used include cellulosic materials, for example sheet materials, such as cardboard, for example proofed internally against penetration by the agent.

The topical applicator and reservoir may be dimensioned and located as desired or necessary in all the above forms for

any particular fluid gel topical scar therapeutic agent,

the desired degree to which a therapeutic agent is to be applied, and

indirect or direct application to a patient on its removal from the medical topical applicator and/or packaging device.

However, the reservoir will usually be from 10mm to 25mm and preferably from 15mm to 20mm in internal diameter. The reservoir will often be from 50mm to 90mm and preferably from 60mm to 80mm in internal length.

The topical scar therapeutic agent will often occupy only part of the available space or void within the reservoir. Often it will fill some 10 to 90%, preferably at least 50% of the space or void.

Suitable fluid gel therapeutic agents will be those providing sufficient therapeutic activity in a dosage convenient for topical application to the patient to reduce scar tissue and/or hinder scar tissue formation effectively, but which have suitable physical properties for this purpose.

Thus, for example suitable agents include any gel that is can secure itself in position on the patient, or dressing if that is desired, without difficulty.

Any suitable fluid gel therapeutic agent materials may be used, for example in particular

fluid siloxane gels, and

fluid alginate gels, for example an alginate-based gel, such as Purilon (TM, Coloplast), and

cellulosic material gels, for example carboxymethylcellulose (CMC) gels, such as Intrasite fluid gel (TM, Smith & Nephew).

However, (depending self-evidently on the physical properties of the gel, such as the viscosity of the gel inter alia, not all gels may be suitable for use in any given device.

More generally suitable fluid gel therapeutic agent materials include mobile polysiloxane gels, and preferably such materials that are novel compositions comprising a silicone fluid, a silicone gum, a silicone wax and a volatile silicone.

More preferred materials include a composition comprising
1-25 wt% of a silicone gum,
1-40 wt% of a silicone fluid having a viscosity of 10 to 60,000mm^2/s,
1-35 wt% of a silicone wax and
1-90 wt% of a volatile silicone fluid having a viscosity up to and including 5mm^2/s.

These compositions have numerous properties that render them useful for the treatment or prophylaxis of scars resulting from injury or surgery and for forming films on the skin.

The latter include, for example, the films being substantive such that they do not smear, transfer to clothing or exhibit cold flow. Similarly, the films are semi-occlusive such that they provide an emollient and moisturising effect.

Additionally, the compositions are aesthetically pleasant in that they are not tacky (i.e., they have a silky feel), they have a mat appearance (i.e., not shiny), they are comfortable when applied, and they are easy to apply and remove.

Of particular significance is the fact that the more preferred compositions can be produced in any form from a liquid to a thick paste and, thus, can be delivered by any conventional means.

The first ingredient of the more preferred compositions are silicone gums.

These gums provide the compositions herein with the ability to form substantive, mat films and, conversely, without such gums the more preferred compositions are sticky and easily removed (e.g., washing or smearing).

Such gums are typically high molecular weight polydimethylsiloxanes terminated with

unreactive groups such as trimethylsiloxy or

reactive groups such as dimethylhydroxysiloxy or dimethylvinylsiloxy.

However, nearly any silicone gum, or mixtures thereof, will function herein. Most preferably, the silicone gum is a dimethylhydroxy- siloxy-terminated polydimethyl-siloxane.

Silicone gums typically have viscosities up to 50 million mm^2/s at 25^0C and have number average molecular weights (Mn) of up to 700,000 or more.

Preferably, the gums have an Mn of about 200,000 to 400,000.

Such gums and methods for their production are known in the art as exemplified by Noll, Chemistry and Technology of Silicones, Academic Press, 1968. In addition, silicone gums are commercially available from, for example, Dow Corning Corporation.

Generally, silicone gums are added to the composition of the invention in amounts of about 1 to 25 wt%. Preferably, silicone gums are used in an amount of about 5 to 15 wt%.

The more preferred compositions also contain silicone fluids having viscosities of about 10 to 60,000 mm^2/s at 25^0C.

These fluids plasticise the compositions herein and improve their spreadability and conformability.

Such fluids are typically linear polydimethylsiloxanes terminated with unreactive groups such as trimethylsiloxy or

reactive groups such as dimethylhydroxysiloxy or dimethylvinyl-siloxy.

However, nearly any silicone fluid, or mixtures thereof, will function herein. This includes, for example, fluids with small amounts of branching or fluids with organic groups other than methyl attached to silicon.

As noted, the silicone fluids herein will have viscosities of about 10 to 60,000mm²/s at 25°C. Preferably, the silicone fluids will have viscosities of about 20 to 20,000mm²/s at 25°C. Most preferably, the silicone fluid comprises a mixture of silicone fluids having viscosities of about 20 and about 12,500mm²/s at 25°C.

Such fluids and methods for their production are known in the art as exemplified by Noll, Chemistry and Technology of Silicones, Academic Press, 1968. In addition, silicone fluids are commercially available from, for example, Dow Corning Corporation.

Generally, silicone fluids are added to the more preferred compositions in amounts of about 1 to 40 wt%. Preferably, silicone fluids are used in an amount of about 20 to 30 wt%.

The more preferred compositions also contains silicone waxes.

These waxes provide the compositions herein with their silky, non-tacky and semi-occlusive properties. The occlusive property, in turn, provides skin hydration, which is a major factor in scar treatment or prophylaxis.

These waxes also act as a hardening lubricant that causes a reduction in the elastic contribution of the gums under stress and a reduction in the creep of the film. Nearly any silicone wax, or mixtures thereof, will function herein.

Preferred silicone waxes suitable for use in the more preferred compositions include alkylmethylsiloxane copolymers having the following formulations:

1. $RMeSiO)_a(Me_2SiO)_b$

or

2. $'Me_2(RMeSiO)_y (Me_2SiO)_z SiMe_2R'$

wherein R is C_nH_{2n+1}, R' is R or Me, Me is CH_3, n is 5 to 45, preferably 10-30, a is an integer from 3 to 10, b is an integer of 0 to 10, a + b is 3 to 10 and y and z are independently 0 or a positive integer of, for example, 1-1000, provided the resultant material is waxy in character, i.e., when R' is Me, y must be 1 or greater.

Preferably, the silicone wax comprises a trimethylsiloxy-terminated poly(dimethyl, methyloctadecyl)siloxane.

The silicone waxes of the more preferred compositions typically have melting points of between about 30°C and about 100°C.

Methods for the preparation of such materials are known in the art.

Such methods are described in, for example, US Pat. No. 5,017,221, which issued May 21, 1991, and US Pat. No. 5,160,494, which issued Nov. 3, 1992, both of which are incorporated herein by reference.

Such methods involve the reaction of a linear siloxane having SiH functionality in the chain with a cyclic siloxane containing Me_2SiO units, and contacting the reaction product with a slight stoichiometric excess of an alkene in the presence of a platinum on carbon catalyst.

In addition, silicone waxes are commercially available from, for example, Dow Corning Corporation.

Generally, silicone waxes are added to the more preferred compositions in amounts of about 1 to 35 wt%. Preferably, silicone waxes are used in an amount of about 5 to 15 wt%.

The more preferred compositions also contain volatile silicone fluids having viscosities of up to and including about $5mm^2/s$.

This volatile fluid allows for easy blending and application of the composition to form a thin film without a cold flow effect. While such fluids are typically cyclic or linear polydimethylsiloxanes or permethylsilanes, nearly any volatile silicone fluid, silane, or mixtures thereof, will function herein.

As noted, the volatile silicone fluids generally have a viscosity of up to and including about $5mm^2/s$, and preferably up to about $1.5mm^2/s$ at 25°C such that they volatile in the ambient environment.

Generally, such volatile silicone fluids correspond to the average unit formula $(CH_3)_aSiO_{(4-a)/2}$ where *a* has an average value of from 2 to 3.

Such fluids often comprise siloxane units joined by Si-O-Si bonds selected from the group consisting of $(CH_3)_3SiO_{1/2}$ and $(CH_3)_2SiO_{2/2}$units taken in such molar amounts so that there is an average of from approximately two to three methyl groups per silicon in the fluid.

The volatile silicone fluids of the more preferred compositions can also bear a permethylsilane corresponding to the average unit formula $(CH_3)_aSi$ where *a* has an average value of from 2 to 3.

Such fluids comprises silane units joined by Si-Si bonds selected from the group consisting of $(CH_3)_3Si$ and $(CH_3)_2Si$ units taken in such molar amounts so that there is an average of from approximately two to three methyl groups per silicon in the fluid.

Preferably the silicone fluid consists essentially of dimethylsiloxane units, and optionally, trimethylsiloxane units.

Of particular interest in the more preferred compositions are methylsiloxane fluids such as the cyclopolysiloxanes of the general formula $\{(CH_3)_2SiO\}_x$ and linear siloxanes of the general formula $(CH_3)_3SiO\{(CH_3)_2SiO\}_ySi(CH_3)_3$ wherein *x* is an integer of from 4 to 6 and *y* is an integer of from 0 to 4.

Preferred silicone fluids or blends of silicone fluids include cyclic silicones such as hexamethylcyclotrisiloxane, octamethylcyclotetra-siloxane, decamethylcyclopentasiloxane.

They also include linear silicones such as hexamethyldisiloxane, octamethyltrisiloxane, decamethyltetrasiloxane.

The preferred volatile silicone fluid is hexamethyldisiloxane.

These volatile silicone fluids and methods for their manufacture are known in the art as exemplified by Noll, Chemistry and Technology of Silicones, Academic Press, 1968.

In addition, these volatile silicone fluids are commercially available from, for example, Dow Corning Corporation.

Generally, the volatile silicone fluids are added to the more preferred compositions in amounts of about 1 to 90 wt% and preferably 40 to 70 wt%.

The more preferred compositions may be prepared by simply mixing the components in any desired order.

Apparatus such as stirrers, blenders, mills and the like, and any other means known in the art can be used. In addition pressure vessels, condensing systems and other means known in the art and commonly used to retain a volatile component in a mixture may be employed in the preparation of the more preferred compositions.

By changing the ratio of components in the more preferred compositions, one has great flexibility in producing compositions with a wide range of physical properties and, thus, a wide range of utilities.

For example, compositions from liquids to pastes can be produced and these compositions can be changed to suit the type of scar.

Similarly, the compositions may be changed for uses outside scar treatment or prophylaxis such as in cosmetics, skin care, pharmaceutical delivery and the like.

The more preferred compositions can optionally comprise other ingredients such as additional diluents, dispersants or carriers, emollients, humectants, thickeners, fillers, preservatives, stabilisers, buffer systems, plant extracts, amino acids, activity enhancers, cosmetic ingredients such as colorants, perfumes, emulsifiers, and sunscreens and pharmaceutical agents.

Pharmacologically active agents may be included, for example pharmacologically acceptable

preservatives,

sunscreens,

antimicrobial agents, such as chlorhexidine, silver salts, for example silver sulphadiazine, and iodine compounds,

antibiotics, for example metronidazole, and

enzymes, growth factors, and molecular sieves,

usually dispersed throughout the bulk of the therapeutic agent.

As noted above, the therapeutic agent may be applied directly to a patient on its removal from the medical topical applicator and/or packaging device.

Alternatively, it may be intended that topical application of the therapeutic agent may be effected on the agent's removal from the topical applicator and/or packaging device to an absorbent dressing.

In one embodiment of the first aspect of the more preferred compositions there is provided a topical applicator and/or packaging device characterised in that the device removably houses an absorbent dressing.

It is so arranged that on its removal from the topical applicator and/or packaging device the absorbent dressing is coated over at least part of its absorbent surfaces with the topical scar therapeutic agent.

Suitable among the topical applicator and/or packaging devices hereinbefore described for housing and dispensing the container absorbent dressing, and suitable adaptations to coat it, will be clear to the skilled person.

It may be preferred for it to have a frangible or collapsible intervening wall or barrier, as hereinbefore described, to divide, separate or otherwise isolate the reservoir containing the therapeutic agent from the dressing up to the point of dispensation.

According to a second aspect of the more preferred compositions there is provided a process for manufacturing a charged applicator and/or packaging device of the first aspect of the more preferred compositions, characterised by in any convenient or advantageous order

a) constructing a reservoir for a fluid gel topical scar therapy agent,

b) providing an applicator means for removal of the fluid gel topical scar therapeutic agent from the medical topical applicator and/or packaging device, adapted and in such spatial relationship with the reservoir as to coat a patient or a dressing surface with the fluid gel therapeutic agent from the reservoir, and

c) housing a fluid gel topical scar therapy agent in the reservoir.

An applicator and/or packaging device as hereinbefore described can be manufactured by any conventional techniques and processes for manufacturing applicator and/or packaging devices.

For example, in one case, desirably a roller-ball applicator means chamber (without the roller-ball) and reservoir (without any end wall) are formed as a unit in a single process step.

One such an applicator and/or packaging device, for example, is made of a flexible synthetic polymer, such as a thermoplastic, for example a polyester (e.g. PET) or polyamide (for example nylon™), or polyalkylene.

It maybe constructed, for example cast, moulded or extruded conventionally, with the roller-ball applicator means chamber (without the

roller-ball) and reservoir (without any end wall) all constructed integrally. This may be done for example by liquid injection moulding.

The ball may then be snap-fitted into the applicator means chamber to be housed in it. The scar therapeutic agent (for example a polysiloxane fluid gel, such as oar) may be introduced into the reservoir.

The desired wall at the end of the reservoir may be fixed in position by heat-sealing or welding (which is particularly apt for thermoplastic materials).

Ways of incorporating the scar therapeutic agent into a topical applicator and/or packaging device will vary with the physical nature of the device and the scar therapeutic agent.

Such ways include forcing the scar therapeutic agent into the reservoir by blowing.

Where the device is a syringe, the reservoir syringe barrel may be cast, moulded or extruded conventionally, for example from a thermoplastic, for example a polyester (e.g. PET) or polyamide (for example nylon™), polypropylene or a polyethylene, polysiloxane or other polymer materials.

After insertion of the gel, the reservoir may be slidably plugged or stopped by a driving means, such as a piston or plunger adapted to sweep the inside of the reservoir in an inward stroke.

The applicator and/or packaging device in both above embodiments may alternatively be made of cellulosic materials, for example sheet materials, such as cardboard, for example proofed internally against penetration by the agent.

In this case, desirably the reservoir is formed as a unit in a single process step, for example by rolling a sheet, for example a rectangular sheet, of cardboard.

This forms the shell of the desired reservoir as a single hollow cylindrical rolled barrel. This may be fixed by, for example doubling over or tucking the ends of the roll together and crimping them, optionally with one or more adhesive fillets and/or adhesive tape, bands or strips.

Any desired wall at the outlet end of the reservoir may then be fixed in position, generally with one or more adhesive fillets and/or adhesive tape, bands or strips.

Ways of introducing the scar therapeutic agent into a syringe applicator will generally be as described immediately above.

In the form of this process for assembling an applicator and/or packaging device in the form of a blister pack, the device of the second aspect of the more preferred compositions may be made be made by the following process steps:

Using a hot lamination process, a blister film, membrane or sheet having a plurality or multiplicity of spaced blisters in arrays of rows. may be manufactured from a transparent film, membrane or sheet.

Immediately after forming the arrays of transparent blisters, the scar therapeutic agent (such as a fluid polysiloxane gel, for example the preferred such materials described hereinafter) is inserted into each blister to fill the arrays of blisters.

Then a closure foil is then placed over the blister array or foil-plastics film, membrane or sheet laminate. This is then attached, for example heat-laminated between the arrayed blisters, to form a laminate of the transparent film, membrane or sheet to the foil.

In a third aspect of the more preferred compositions there is provided a method of treating scar formation or formed scars characterised by applying a fluid gel topical scar therapeutic agent topically to a patient.

In one embodiment of the third aspect of the more preferred compositions the treatment or prophylaxis is provided using a topical

applicator and/or packaging device of the first aspect of the more preferred compositions.

In another embodiment of the first aspect of the more preferred compositions, the treatment or prophylaxis is provided using a fluid gel topical scar therapy agent that is a polysiloxane, such as the preferred such materials described hereinafter.

The following non-limiting examples are provided so that one skilled in the art can appreciate the aptness of the more preferred compositions to the present method of topical scar treatment or prophylaxis using a composition that forms a film on the skin.

Example 1

The present example shows the moisture vapour transmission rate for more preferred compositions and comparative materials.

Composition A was prepared by thoroughly mixing

26.38g of dimethylhydroxysiloxy-terminated polydimethylsiloxane gum having an Mn of about 300,000;

18.67g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 12,500mm²/s;

37.04g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 20mm²/s and

17.9g of trimethylsiloxy-terminated poly(dimethyl, methyloctadecyl)-siloxane wax having a melting point of 32°C.

43g of composition A was dispersed into 57g of hexamethyldisiloxane.

Composition B was prepared by thoroughly mixing

26.2g of dimethylhydroxysiloxy-terminated polydimethylsiloxane gum having an Mn of about 300,000;

19.2g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 12,500mm²/s;

36.8g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of 20mm²/s and

17.8g of trimethylsiloxy-terminated poly(dimethyl, methyloctad-siloxane wax having a melting point of 32°C.

43g of composition B was dispersed into 57g of hexamethyldisiloxane.

A comparative composition C was prepared by thoroughly mix

26.2g of dimethylhydroxysiloxy-terminated polydimethylsiloxane having an Mn of about 300,000;

19.2g of trimethylsiloxy-terminated polydimethylsiloxane fluid hvg a viscosity of 12,500mm^2/s and

36.8g of trimethylsiloxy-terminated polydimethylsiloxane fluid hvg a viscosity of 20mm^2/s.

43g of composition C was dispersed into 57g of hexamethyldisiloxane.

A second comparative composition D comprised lot 1128/107 the commercial gel Kelocote™ from Allied Biomedical, Paso Robles, C.

Each of these materials, compositions A, B, C and D, were tested for moisture vapour transmission rate.

The experiment was based on the ASTM E96-95 entitled "Stand Test Methods for Water Transmission of Materials" and conducted according to the following parameters:

1) About 14.5mg/cm² of tested material was coated with a handcoater onto a 55mm diameter disc made from a microporous membrane that supports the material during the test.

The microporous membrane is a PET membrane with a average pore size of 0.2µm from 3M™ referenced as 3M™ CoTran™ Membrane.

2) Each coated disc was put onto a cylindrical cup (h # 40mm, # 40mm) which contains 20ml of demineralised water.

3) The trials were done in a climatic system at a temperature of 32°C and at 50% relative humidity. The results are shown in Table 1.

Table 1 :

Composition	Coated weight (mg/cm^2)	MVTR ($g/m^2.24h$)
A	14.9	112.4
B	14.1	109.4
C	13.5	183.5
D	15.9	175.5
blank (membrane CoTran)	0	2625.7

MVTR = Moisture Vapour Transmission Rate

Example 2

The present example shows the oxygen permeability for materials of the more preferred compositions and comparative materials.

Composition A and comparative compositions C and D were prepared as in Example 1.

Each of these materials was tested for oxygen permeability. The experiment was based on a chromatographic method as documented in the ISO/CD 15105-2 and conducted according to the following parameters:

1) About $17.2mg/cm^2$ of tested material was coated with a handcoater onto a 55mm diameter disc made from a microporous membrane that supports the material during the test. The microporous membrane is a PET membrane with an average pore size of 0.2μm from 3M™ referenced as 3M™ CoTran 9711 Membrane.

2) Each coated disc was put into the chromatography cell to form a $0.5cm^2$ interface between a flow of helium as chromatographic carrier gas and a flow of gas at atmospheric pressure containing 50% oxygen.

3) The trials were done at a temperature of 23°C and at 0% relative humidity. The results are shown in Table 2.

Table 2 :

Composition	Coated weight (mg/cm^2)	Oxygen gas permeability ($cm^3/m^2.24h.bar$)
A	15.4	52,000
C	19.5	201,600
D	16.8	201,600
blank (membrane CoTran) based on standard NF Q 03076	0	around 10^{10}

Example 3

The present example shows the rheological behaviour for materials of the more preferred compositions and comparative materials.

Composition A was made by the process described in Example 1.

Comparative composition E was prepared by thoroughly mixing

262.1g of dimethylhydroxysiloxy-terminated polydimethylsiloxane gum having an Mn of about 300,000;

192g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of $12,500mm^2/s$ and

368g of trimethylsiloxy-terminated polydimethylsiloxane fluid having a viscosity of $20mm^2/s$.

43g of composition E was dispersed into 57g of hexamethyldisiloxane.

A second comparative composition F comprises only dimethylhydroxysiloxy-terminated polydimethylsiloxane gum having an Mn of about 300,000.

Each of these materials was tested for its rheological behaviour. The experiment was conducted by recording the elastic and loss moduli of a 0.5ml sample with a controlled stress rheometer (Carrimed™ CSL 500 from TA Instrument) equipped with a two-parallel plate geometry spaced from 100µm and the upper plate has a 2cm diameter. The test conditions

were 1.75.10^{-2} rad strain for 2 hours under 1 Hz at 25°C. The results are shown in Table 3.

Table 3 :

Composition	G' (Pa)	G" (Pa)
A	1,700	1,400
E	2,400	1,200
F	22,200	26,400